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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,443	08/14/2001	Jack Price	GJE-74	9647

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,443	PRICE, JACK	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,24-26,29-43 and 46-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,24-26,29-43 and 46-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 21, 24-26, 29-43 and 46-58 are pending in the application.

This Office Action is in response to the Amendment filed on 1/3/06.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/3/06 has been entered.

Response to Amendment

The objection to claim 45 is moot in light of the cancellation.

The rejection of claims 21, 23-30 under 35 U.S.C.102 (b) has been withdrawn in light of Applicant's amendment.

Claims 21, 24-26, 29-43 and newly added claims 46-58 stand rejected under 35 U.S.C. 112 1st paragraph for reasons set forth of the record mailed on 7/28/05 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 21, 24-26, 29-43 and 46-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicant argues that claims drawn to conditionally immortal hematopoietic stem cells and composition comprising said cells are useful *in vitro* or *in vivo* for many of the same purpose as other HSC, such as being expanded for differentiation, wherein the differentiated cells may be used as a source of various blood cell types or hematopoietic protein, and HSC can also be used to treat patients with cancers and disorders or the blood and immune system. Applicant asserts that the amended claims recite that conditional immortality is conferred to the cells by an oncogene regardless of how said oncogene is introduced. Applicant further asserts the NIH report cited by Examiner indicates that human HSC have been used clinically for several years, and human HSC is used for cell-based gene therapy in clinical trials. Moreover, Applicant asserts that the enablement does not require that the starting material for an invention be abundant, only sufficient quantities to carry out the invention, wherein the state of art does not prevent the use of these cells in cell based gene therapy trials. Furthermore, Applicant asserts that the Examiner gives no reason to doubt why methods used to conditionally immortalize other cells in the prior art could not be applied to human HSC, and why the administered HSC would function consistent with a neural phenotype. Lastly, Applicant argues that three applications that claim priority to WO 97/10329 was filed, and a notice of allowance has been mailed to the Applicant for the 09/760,274 application. Applicant thus concludes that the claimed invention is enabled by the instant specification.

The above arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement of the instant claims are discussed in detail in the previous office action mailed on 7/28/05. The amended claims 21, 24-26, 29 and 30 are drawn to an isolated conditionally immortal human hematopoietic stem cell (HSC), wherein said cell comprises an

introduced oncogene that confers conditional immortality to said HSC. As discussed in the previous office action, the statue of 112 1st paragraph requires the claimed invention is described sufficiently so that one skilled in the art would be able to make and use the claimed invention without undue experimentation. A review of the instant specification reveals that the teaching with regard to conditional immortalization of the HSC is very limited. The specification only discloses making said conditionally immortal HSC by transduce the cells with an oncogene. Applicant's argument of whether the oncogene is resulted from transduction or other methods is unpersuasive. The examiner has never stated that the oncogene must be introduce by a certain method, however, the 112 1st statue requires the specification to teach how to make and use the claimed invention. In the instant case, the specification needs to teach how this oncogene is introduced to the human HSC and confers conditional immortality to said cells. The office action mailed on 7/28/05 has given a thorough *Wands* analysis including nature of the invention, teaching of the specification, the breadth of the claim, the teaching of the prior art, the level of predictability in the prior art and amount of experimentation required. Applicant's remark the office failed to provide a reason why the claimed invention is not accurate (please refer to page 5 and 6 of the previous office action). Further, Applicant's argument regarding use of HSC in clinical application is irrelevant to the instant rejection because the claimed subject matter is not directed to use HSC in any clinical application, but a conditional immortalized human HSC that comprises an oncogene, and a method of treating cognitive deficit associated with brain damage by using HSC. As discussed previously, for the claimed method, a therapeutic effect need to be demonstrated since the claims are drawn to a method of treating wherein cognitive function is improved in the patients. Similarly, the specification has to teach how to make the claimed

composition. Applicant's characterization of the state of art regarding HSC therapy for treating neuronal disorder such as cognitive deficit is not accurate because the art clearly teaches the success of such therapy is unpredictable even 5 years after the application was filed. Priller II, the review article provided by Applicant, states "the apparent plasticity of BM stem cells has raised hopes for their use in cell-based repair strategies in the CNS...While the clinical potential of BM stem cell therapy is apparent, there is much to be learnt about the basic biology of stem cell plasticity before we can fully acknowledge the value of bone marrow stem cells in the brain." As such, based on the teaching of this article, whether treating cognitive deficit associated with brain damage by HSC is still unpredictable at present, and Applicant's argument with regard to art does not prevent use of the HSC for cell based gene therapy is complete off the point. Lastly, Applicant is reminded that issued patents are property, not precedent, and each application is considered on its own merits. As such, applying for a patent of a related subject matter does not automatically support the enablement of the instantly claimed invention. A review of the application 09/760,274, the one which a notice of allowance was mailed, reveals that the claimed subject matter is a method of treating brain damage in a mammal using a specific type of neuroepithelial cells, the examiner is confused how is this application relevant in supporting the enablement of the transduction of human HSC with oncogene to confer conditional immortality, or treating cognitive deficit by HSC, a different cell type. As such, for reasons discussed in the previous office action and above, the claimed invention is not enabled by the instant specification. Therefore, this rejection is maintained.

Claims 46-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In addition to lack of enablement rejection above, claims 46-56 are further rejected for comprising new matter. Contrary to Applicant's assertion, the teaching of the specification, specifically on page 2, lines 4-21; page 3, lines 10-19, page 5, lines 9-18, page 6, lines 3-15, as pointed out in the remarks (see page 6, last paragraph), does not provide support for the claimed method for treating any brain damage. The teaching only provides support for treating a sensory/motor/cognitive disorder associated with brain damage. Therefore, the newly presented claims 46-56 contains new matter which is not adequately described in the instant specification.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER